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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/734,221 | 12/11/2000 | Dan R. Littman | 1049-1-004n2 | 6077 |
| 7590 | 06/15/2005 | | EXAMINER | |
| Klauber & Jackson 411 Hackensack Avenue Hackensack, NJ 07601 | | | LI, BAO Q | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1648 | |

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/734,221 | LITTMAN ET AL. | |
| | Examiner | Art Unit | |
| | Bao Qun Li | 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 March 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-26,33-40 and 61-74 is/are pending in the application.
- 4a) Of the above claim(s) 1-26,33-36,38-40 and 61-73 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 37 and 74 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed 03/23/05. Specification has been amended.

Claim 37 has been amended. Claim 74 has been added. Claims 1-26, 33-40, 61-74 are pending.

Claims 37, 70 and 74 are considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Terminal Disclaimer

In response to the Obvious Double patenting, Applicants filed TD. The TD has been approved and accepted. The ODP rejection is, therefore, withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 37, 70 and 74 are still rejected under 35 U.S.C. 112, first paragraph under the same ground as stated in the previous Office Action, because the specification, while being enabled for having a method of screening an HIV-1 macrophage tropic (HIV M-tropic) fusion inhibitor with cells expressing both CD4 and CCR5 in the presence of M-tropic HIV-1 infection or a virus pseudotyped with a full-length of HIV M-tropic envelope protein, wherein the inhibitor can be used for treating a patient infected with a M-tropic HIV virus sensitive to the said inhibitor, does not reasonably provide enablement for a method of screening any or all HIV fusion inhibitor with a cell that only expresses CCR5 in the presence of any or all kinds of HIV isolates or any or all kinds of viruses pseudotyped with any or all kind of M-tropic envelope, wherein an inhibitor identified by the method can be used for prevention of AIDS. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

3. Applicants traverse the rejection and submitted that claim 37 have amended as a method of identifying an agent that inhibits an HIV infection caused by a macrophage-tropic virus whose entry into cells is mediated by CCR5. Therefore applicants assert that the rejection should be withdrawn. Applicants' amendment as well as argument has been respectfully considered; however, it is not persuasive because this amendment does not overcome the rejection in that the scope of method read on a method for identifying agent for preventing HIV infection. Since claims 37 ("claim 6" in the previous office action is inadvertently a typographic error) and 74 are still drafted as a reach-through claims and the claims do not comply with the "how to make" prong of the enablement requirement for the reasons analyzed by weighting 7 factors outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again *In re Wands*, 8USPQ2d 1400 (Fed. Cir. 1988). The rejection is maintained unless Applicants amend claims by deleting the recitation of "preventing".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claim 37 is still rejected under 35 U.S.C. 102(a) as being anticipated by Cocchi et al. (Science 1995, Vol. 270, pp. 1811-1815) in light of Moriuchi et al. (J. Immunol. 1997, Vol. 159, pp. 5441-5449) on the same ground as stated in the previous Office Action.

6. Applicants traverse the rejection and submitted that according to the Federal Circuit citing the review article of Feit et al. (2003, J. Pat. Trade Off. Soc., Vol. 85, No. 1, pages 5-21), and the three conditions of 1). Certainty; 2), Chronology, and Recognition, the reference of Cocchi et al does not teach each and every limitations of claimed method. Moreover, at the time the Cocchi et al. reference was published, the CCR5 receptor had not yet been identified as HIV macrophage tropic fusion cofactor yet.

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7. Applicants' argument has been respectfully considered; however, it is not found persuasive because the reference of Cocchi et al. do teach each and every limitations of claimed method.

8. The claimed method for identifying an agent whether or not it can influence the HIV-1, preferably M-tropic HIV-1 envelope fusion or entry into a target cell comprise three elements, (a) contacting an agent with a cell having a CCR5 expressing on the cell surface in the presence of an HIV virus or a virus psuedotyped with an HIV macrophage-envelope, (b) measuring whether the agent can inhibit the virus fused with the target cell significantly or the cell gets a resistance to the virus fusion or entry and (c) selecting the agent by measuring said cell to resist fusion with and/or entry to the macrophage-tropic HIV virus in comparison with a group of another cell-virus infection system that does not contain the test agent.

9. The method disclosed by Cocchi et al. contains all three elements (1) contacting the agent (recombinant human C-C-chemokine selected from group consisting of recombinant human RANTES (rhRANTES) or MIP-1 α (rh MIP-1 α), or MIP-1 β (rh MIP-1 β) or MCP-1) with MP1 cell line in the presence of M-tropic HIV-1, such as HIV-1_{Bal} or T-tropic HIV-1 virus, (2). They demonstrate that inhibitory effect of test agent chemokine rhRANTES, rhMIP-1 α and rhMIP- β , against both T-tropic and M-tropic HIV infection, and 3). They conclude that the M-tropic HIV-1_{Bal} infection is inhibited by the c-chmokines; rhRANTES or rhMIP-1 α , rhMIP- β .
10. Regard to argument that time of identifying CCR5 as M-tropic HIV fusion-cofactor, Feit et al. indicate that it is irrelevant whether it was apparently at the time of filling the application in question. Therefore, the rejection is remained.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

06/11/2005


JAMES C. HOUSEL 6/13/05
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